UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

PAUL HILLS,	)	
	)	
Plaintiff,	)	
	)	
	)	
v.	)	No. 08 CV 3329
	)	Judge Joan Humprey Lefkow
BAXTER HEALTHCARE CORP.,	)	
BAXTER INTERNATIONAL INC. and	)	
WYETH SUBSIDIARY ILLINOIS	)	
CORPORATION F/K/A SCIENTIFIC	)	
PROTEIN LABORATORIES,	)	
	)	
Defendants.	)	

ANSWER OF BAXTER HEALTHCARE CORPORATION AND BAXTER INTERNATIONAL INC.

Defendants, BAXTER HEALTHCARE CORP. ("BHC") and BAXTER INTERNATIONAL INC. ("BII"), by and through their attorneys, KIRKLAND & ELLIS, LLP, respond to Plaintiff Paul Hills' Complaint as follows:

COUNT I
BAXTER HEALTHCARE INTERNATIONAL, INC.
(WRONGFUL DEATH-STRICT LIABILITY)

The Parties

1. Plaintiff, Paul Hills, was at all relevant times was a resident of Evanston, Illinois, Cook County.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1, Count I of the Complaint and, therefore, deny the same.

2. Defendant, Baxter Healthcare Corporation has its principle [sic] place of business at One Baxter Parkway in Deerfield, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 2, Count I of the Complaint.

3. Defendant, Baxter International Inc. has its principle [sic] place of business at One Baxter Parkway in Deerfield, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 3, Count I of the Complaint.

4. At all relevant times, the registered agent for Baxter Healthcare Corporation was CT Corporation located in Cook County, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 4, Count I of the Complaint.

5. At all relevant times, the registered agent for Baxter International was CT Corporation located in Cook County, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 5, Count I of the Complaint.

6. Scientific Protein Laboratories is a corporation which produces ingredients for intravenous heparin. Scientific Protein Laboratories has its principle [sic] place of business in Waunakee, Wisconsin.

ANSWER:

Upon information and belief, BHC and BII admit the allegations of Paragraph 6, Count I of the Complaint.

7. At all relevant times, Baxter Healthcare Corporation was in the business of designing, manufacturing and distributing intravenous Heparin for profit.

ANSWER:

BHC and BII deny the allegation that Baxter Healthcare Corporation designs, has designed or was "in the business of designing" intravenous heparin. BHC and BII admit the remaining allegation in Paragraph 7, Count I of the Complaint.

8. At all relevant times, Baxter Healthcare Corporation marketed and advertised is [sic] pharmaceutical sales within Cook County.

ANSWER:

BHC and BII admit the allegations of Paragraph 8, Count I of the Complaint.

9. At all relevant times, Baxter Healthcare Corporation employed a number of employees that worked within Cook County, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 9, Count I of the Complaint.

10. At all relevant times, Baxter Healthcare Corporation sold millions of dollars worth of pharmaceutical products including intravenous Heparin to healthcare providers in Cook County, Illinois.

ANSWER:

BHC and BII deny the allegations of Paragraph 10, Count I of the Complaint.

Contaminated Heparin

11. Heparin is a prescription drug in a class of medications called anti-coagulants also known as blood thinners.

ANSWER:

BHC and BII admit that heparin is an anticoagulant, also known as a blood thinner. BHC and BII admit that heparin is classed for regulatory purposes as a prescription drug, although heparin is in reality a complex biologic.

12. Heparin is a pork-derived product and one of the oldest drugs currently still in widespread clinical use, having been used since the early 1990s.

ANSWER:

BHC and BII admit that heparin can be a pork-derived product and that it has been used since the at least the early 1990s. BHC and BII admit that heparin is one of the oldest drugs currently still in widespread clinical use.

13. Heparin works by decreasing the clotting ability of the blood, thereby preventing the actual formation of clots or preventing the extension of existing clots within the blood.

ANSWER:

BHC and BII admit the allegations of Paragraph 13, Count I of the Complaint.

14. It is most often administered intravenously and is used primarily to decrease the chance of clots forming in patients undergoing certain medical procedures such as cardiac surgery, in preventing the formation of clots in catheters (small plastic tubes through which medication is administered or blood drawn) such as in kidney dialysis, and for other such conditions like pulmonary emboli.

ANSWER:

BHC and BII admit the allegations in Paragraph 14, Count I of the Complaint but note that heparin is also administered subcutaneously and for other medical purposes.

15. The Food and Drug Administration ("FDA") estimates that more than 1 million multiple-dose vials are sold each month in the United States.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 15, Count I of the Complaint and, therefore, deny the same.

16. Baxter is one of the largest producers of Heparin in the United States, and its sales of heparin constitute at least a 50% market share.

ANSWER:

BHC and BII admit that Baxter Healthcare Corporation is one of the largest producers of heparin in the United States and that Baxter supplies approximately half of the multi-dose vials of heparin used in the United States. BHC and BII deny the remaining allegations of Paragraph 16, Count I of the Complaint.

17. Baxter sells an estimated 35 million units of Heparin per year, with annual sales of approximately $30 million dollars.

ANSWER:

BHC and BII admit that Baxter Healthcare Corporation sells approximately 35 million units of heparin sodium injection multi and single dose vials per year in the United States, with an annual sales value of approximately $30 million.

18. Baxter reported total sales in the amount of $11.3 billion dollars for 2007, with over 70% of its revenues being sourced form products in market-leading positions.

ANSWER:

BHC and BII admit that Baxter International Inc. reported net sales of $11.3 billion for 2007. BHC and BII deny the remaining allegations of Paragraph 18, Count I of the Complaint.

19. The multiple-dose heparin vials were represented by Defendants to be safe and effective for their intended uses, including, but not limited to, intravenous administration during hemodialysis.

ANSWER:

BHC and BII provided written labels and warnings with its multiple-dose heparin vials as required by law that speak for themselves. BHC and BII deny the remaining allegations of Paragraph 19, Count I of the Complaint.

20. The multiple-dose heparin vials were defective in their manufacture.

ANSWER:

BHC and BII deny the allegations of Paragraph 20, Count I of the Complaint.

21. Defendants are designers, developers, manufacturers, wholesales, retailers, fabricators, suppliers and/or distributors of the multiple-dose heparin vials, one or more of which was administered to the Paul Hills during a hemodialysis session or sessions.

ANSWER:

BHC and BII admit that they manufacture and supply multiple-dose heparin vials. BHC and BII deny that they are designers, developers, wholesalers, retailers or distributors of heparin. BHC and BII are without knowledge or information sufficient to form a belief as to the allegation that heparin from their multiple dose vials was administered to Plaintiff and, therefore, deny the same.

22. The multiple-dose heparin vials were manufactured, fabricated, distributed, supplied and/or placed in the stream of interstate commerce by Defendants.

ANSWER:

BHC and BII admit that they manufacture and supply multiple-dose heparin vials. BHC and BII deny the remaining allegations of Paragraph 22, Count I of the Complaint.

23. Defendants obtained the component parts for the multiple-dose heparin vials from unidentified supply companies, including, but not limited to, Scientific Protein Laboratories, which has two plants which supply the active pharmaceutical ingredient for heparin to Defendants.

ANSWER:

BHC and BII admit that they obtained the active pharmaceutical ingredient (API) for its multiple-dose heparin vials from Scientific Protein Laboratories. BHC and BII deny that they obtained heparin API from any "unidentified" or "unknown" supply companies. BHC and BII are without information or knowledge sufficient to form a belief as to the remaining allegations of Paragraph 23, Count I of the Complaint and, therefore, deny the same.

24. The active pharmaceutical ingredient in heparin is an enzyme that is extracted from pig intestines.

ANSWER:

BHC and BII admit the allegations of Paragraph 24, Count I of the Complaint.

25. One of these plants is located in China and upon information belief, has not met the requisite requirements for importation and/or sale within the United States.

ANSWER:

BHC and BII deny the allegations of Paragraph 25, Count I of the Complaint.

26. Such requirements include, but are not necessarily limited to, inspection and approval by the Food and Drug Administration as is required for any facility to supply drug ingredients to the United States.

ANSWER:

Paragraph 26, Count I of the Complaint contains legal conclusions to which BHC and BII do not believe a response is due. To the extent that response is required, BHC and BII deny the allegations of Paragraph 26, Count I of the Complaint.

27. Upon information and belief, Defendants knew or should have known of such non-compliance or lack of plant inspection and/or approval, which is required for all foreign facilities.

ANSWER:

BHC and BII deny the allegations of Paragraph 27, Count I of the Complaint.

28. Such multiple-dose heparin vials were defective at the time they were placed in the stream of commerce.

ANSWER:

BHC and BII deny the allegations of Paragraph 28, Count I of the Complaint.

29. Baxter knew or should have known that these multiple-dose heparin vials were defective at the time they left Baxter's control and custody.

ANSWER:

BHC and BII deny the allegations of Paragraph 29, Count I of the Complaint.

30. Defendants also knew or should have known that the multiple-dose heparin vials were causing adverse reactions for patients, such as Paul Hills.

ANSWER:

BHC and BII deny the allegations of Paragraph 30, Count I of the Complaint.

31. Notwithstanding their knowledge, Baxter continued to supply and sell the multiple-dose heparin vials up to and until just recently, without providing any warnings about the risks and drugs associated with the multiple-dose heparin vials to members of the public and the medical community, including Paul Hills.

ANSWER:

BHC and BII deny the allegations of Paragraph 31, Count I of the Complaint.

32. At all material times, Baxter intentionally concealed from the public and members of the medical community, including Paul Hills, the risks and dangers associated with the use of the multiple-dose heparin vials, and/or has misrepresented the safety, quality and performance of multiple-dose heparin vials.

ANSWER:

BHC and BII deny the allegations of Paragraph 32, Count I of the Complaint.

33. On or about January 17, 2008, Baxter and the FDA both issued press releases regarding the voluntary recall by Baxter of nine lots of Heparin Sodium Injection multiple dose vials in 1000 units/mL concentrations of 10mL and 30mL vials, 5000 units/mL concentration of 10mL vials and 10,000 units for 4mL vials.

ANSWER:

BHC and BII admit that on or about January 25, 2008, Baxter Healthcare Corporation issued a press release discussing the voluntary recall of nine lots of heparin sodium injection 1000 units/mL 10mL and 30mL multi-dose vials as a precautionary measure. BHC and BII deny the remaining allegations of Paragraph 33, Count I of the Complaint.

34. This voluntary recall was the result of an abnormal increase in the reports of adverse patient reactions associated with the use of heparin.

ANSWER:

BHC and BII admit that Baxter Healthcare Corporation initiated the voluntary recall as a precautionary measure due to an increase in the number of reports of adverse patient reactions that may be associated with the use of heparin. BHC and BII deny the remaining allegations of Paragraph 34, Count I of the Complaint.

35. These adverse patient reactions included the following: allergic or hypersensitivity-type reactions, with symptoms of oral swelling, abdominal pains, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, and unresponsiveness to stimul [sic], as well as cases of severe hypotension requiring treatment.

ANSWER:

BHC and BII admit that reported adverse patient reactions included oral swelling, abdominal pains, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal

edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, hypotension, and unresponsiveness to stimuli. BHC and BII deny the remaining allegations of Paragraph 35, Count I of the Complaint.

36. These adverse reports began as early as November 19, 2007, from more than nineteen dialysis facilities in more than twelve states.

ANSWER:

BHC and BII deny the allegations of Paragraph 36, Count I of the Complaint.

37. An estimated 40% of the adverse reports have been categorized as serious by the FDA and there have been at least four reported deaths.

ANSWER:

BHC and BII admit that at least four deaths have been reported but deny a causal relationship between the allergic reactions involved in the heparin recall and the four fatalities. BHC and BII deny the remaining allegations of Paragraph 37, Count I of the Complaint.

38. The bulk of the adverse reports have centered on adverse events occurring at hemodialysis centers.

ANSWER:

BHC and BII deny the allegations of Paragraph 38, Count I of the Complaint.

39. According to the FDA, there has been a significant increase in reported adverse events associated with the use of Heparin, with an estimated 350 events reported since December 2007 in contrast to less then 100 reports in 2007.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 39, Count I of the Complaint and, therefore, deny the same.

40. Based upon the clusters of adverse reports, Baxter and the Center for Disease Control ("CDC") initially identified nine specific Heparin manufacturing lots with a suggested link to those cases.

ANSWER:

BHC and BII admit the allegations of Paragraph 40, Count I of the Complaint.

41. The initial nine lots recalled by Baxter ware [sic] for the following Heparin products: NDC#00641-2440-45, NDC#00641-2440-41, NDC#00641-2450-45, and NDC#00641-2450-41. The products include the following lots:

a. Heparin 1000 units/mL, l0mL vial, expiration date 10/2009, Lot #107054
b. Heparin 1000 units/mL, 10mL vial, expiration date 11/2009, Lot #117085
c. Heparin 1000 units/mL, 30mL vial, expiration date 10/2008, Lot #047056
d. Heparin 1000 units/mL, 30mL vial, expiration date 9/2009, Lot #097081
e. Heparin 1000 units/mL, 30mL vial, expiration date 10/2009, Lot #107024
f. Heparin 1000 units/mL, 30mL vial, expiration date 10/2009, Lot #107064
g. Heparin 1000 units/mL, 30mL, expiration date 10/2009, Lot #107066
h. Heparin 1000 units/mL, 30mL, expiration date 10/2009, Lot #107074
i. Heparin 1000 units/mL, 30mL, expiration date 10/2009, Lot #107111

ANSWER:

BHC and BII admit the allegations of Paragraph 41, Count I of the Complaint.

42. Upon information and belief, these nine lots were all manufactured at a single facility between September and November of 207 [sic].

ANSWER:

BHC and BII admit that the nine lots listed in Paragraph 41 were manufactured at Baxter Healthcare Corporation's Cherry Hill facility. BHC and BII deny the remaining allegations of Paragraph 42, Count I of the Complaint.

43. Upon information and belief, the active pharmaceutical ingredient in these products was at least in part provided by a third party supplier from an unapproved facility in China.

ANSWER:

BHC and BII deny the allegations of Paragraph 43, Count I of the Complaint.

44. However, according to FDA updates, more recent information indicates that comparable adverse events are continuing to be reported that are associated with the use of multiple-dose heparin vials of different manufacturing lots than those identified in the initial voluntary recall.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 44, Count I of the Complaint and, therefore, deny the same.

45. The FDA began inspections of Baxter's manufacturing plant in Cherry Hill, New Jersey and its processes on or about January 16, 2008.

ANSWER:

BHC and BII admit the allegations of Paragraph 45, Count I of the Complaint.

46. The FDA and CDC are continuing with an investigation to discover the underlying cause of these anomalous adverse events.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 46, Count I of the Complaint and, therefore, deny the same.

47. As of February 11, 2008, Baxter ceased production of all of its multiple-dose vials of injectible heparin due to the potentially life threatening adverse and allergic reactions and incidents of hypotension that are being reported.

ANSWER:

BHC and BII deny the allegations of Paragraph 47, Count I of the Complaint.

Paul Hills

48. On or about July 24, 2007, Paul Hills had a surgical procedure performed for an abdominal aortic aneurysm at Evanston Hospital in Evanston, IL.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 48, Count I of the Complaint and, therefore, deny the same.

49. On or about July 24, 2007, the aforesaid procedure performed on Paul Hills was successful and he was expected at that point in time to have a complete and full recovery.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 49, Count I of the Complaint and, therefore, deny the same.

50. On or about July 24, 2007, Paul Hills was administered the aforesaid contaminated Heparin manufactured by Baxter.

ANSWER:

The allegations of Paragraph 50, Count I of the Complaint are vague and ambiguous. To the extent that a response is required, BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 50, Count I of the Complaint and, therefore, deny the same.

51. Following the July 24, 2007 procedure, Paul Hills manifested signs and symptoms consistent with the administration of contaminated heparin including: dizziness, fainting, stomach and a fast heart rate.

ANSWER:

The allegations of Paragraph 51, Count I of the Complaint are vague and ambiguous. To the extent that a response is required, BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 51, Count I of the Complaint and, therefore, deny the same.

52. On and after July 24, 2007, Paul Hills had an extensive hospitalization due to complications from the contaminated heparin.

ANSWER:

The allegations of Paragraph 52, Count I of the Complaint are vague and ambiguous. To the extent that a response is required, BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 52, Count I of the Complaint and, therefore, deny the same.

53. On and prior to July 24, 2007, Baxter Healthcare manufactured and distributed the aforesaid contaminated Heparin product which was unreasonably dangerous for its intended use and was defective.

ANSWER:

BHC and BII deny the allegations of Paragraph 53, Count I of the Complaint.

54. Prior to July 24, 2007, the aforesaid contaminated Heparin was introduced into the stream of commerce by Baxter Healthcare and/or Baxter International.

ANSWER:

BHC and BII deny the allegations of Paragraph 54, Count I of the Complaint.

55. Prior to July 24, 2007, and at the time Baxter Healthcare and/or Baxter International introduced the aforementioned contaminated heparin into the stream of commerce the heparin contained a material defect.

ANSWER:

BHC and BII deny the allegations of Paragraph 55, Count I of the Complaint.

56. On July 24, 2007 and at the time the contaminated heparin was administered to Paul Hills, the heparin failed to perform in the manner reasonably to be expected.

ANSWER:

The allegations of Paragraph 56, Count I of the Complaint are vague and ambiguous. To the extent that a response is required, BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 56, Count I of the Complaint and, therefore, deny the same.

57. Prior to July 24, 2007, Baxter Healthcare and/or Baxter International failed to adequately warn of the danger of the contamination in the aforementioned contaminated heparin.

ANSWER:

BHC and BII deny the allegations of Paragraph 57, Count I of the Complaint.

58. As a direct and proximate result of Defendants' defective multiple-dose heparin vials, Paul Hills has been injured and incurred substantial damages, including, but not limited to, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

ANSWER:

BHC and BII deny the allegations of Paragraph 58, Count I of the Complaint.

WHEREFORE, plaintiff, PAUL HILLS, by his attorneys, POWER ROGERS & SMITH, demands judgment against Defendant BAXTER HEALTHCARE and/or BAXTER INTERNATIONAL INC., in such sum of money in excess of FIFTY THOUSAND DOLLARS ($50,000.00) as shall represent fair and just compensation.

ANSWER:

BHC and BII deny that Plaintiff is entitled to the relief sought in the final Paragraph of Count I of the Complaint, or any relief whatsoever from BHC and BII.

COUNT II
SCIENTIFIC PROTEIN LABORATORIES
(WRONGFUL DEATH-STRICT LIABILITY)

1. Plaintiff, Paul Hills, was at all relevant times a resident of Evanston, Illinois, Cook County.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1, Count II of the Complaint and, therefore, deny the same.

2. Defendant, Baxter Healthcare Corporation has its principle [sic] place of business at One Baxter Parkway in Deerfield, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 2, Count II of the Complaint.

3. Defendant, Baxter International Inc. has its principle [sic] place of business at One Baxter Parkway in Deerfield, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 3, Count II of the Complaint.

4. At all relevant times, the registered agent for Baxter Healthcare Corporation was CT Corporation located in Cook County, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 4, Count II of the Complaint.

5. At all relevant times, the registered agent for Baxter International was CT Corporation located in Cook County, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 5, Count II of the Complaint.

6. Scientific Protein Laboratories is a corporation which produces ingredients for intravenous heparin. Scientific Protein Laboratories has its principle [sic] place of business in Waunakee, Wisconsin.

ANSWER:

Upon information and belief, BHC and BII admit the allegations in Paragraph 6, Count II of the Complaint.

7. At all relevant times, Baxter Healthcare Corporation was in the business of designing, manufacturing and distributing intravenous Heparin for profit.

ANSWER:

BHC and BII deny the allegation that Baxter Healthcare Corporation designs, has designed or was "in the business of designing" intravenous heparin. BHC and BII admit the remaining allegation in Paragraph 7, Count II of the Complaint.

8. At all relevant times, Baxter Healthcare Corporation marketed and advertised is [sic] pharmaceutical sales within Cook County.

ANSWER:

BHC and BII admit the allegations of Paragraph 8, Count II of the Complaint.

9. At all relevant times, Baxter Healthcare Corporation employed a number of employees that worked within Cook County, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 9, Count II of the Complaint.

10. At all relevant times, Baxter Healthcare Corporation sold millions of dollars worth of pharmaceutical products including intravenous Heparin to healthcare providers in Cook County, Illinois.

ANSWER:

BHC and BII deny the allegations of Paragraph 10, Count II of the Complaint.

Contaminated Heparin

11. Heparin is a prescription drug in a class of medications called anti-coagulants also known as blood thinners.

ANSWER:

BHC and BII admit that heparin is an anticoagulant, also known as a blood thinner. BHC and BII admit that heparin is classed for regulatory purposes as a prescription drug, although heparin is in reality a complex biologic.

12. Heparin is a pork-derived product and one of the oldest drugs currently still in widespread clinical use, having been used since the early 1990s.

ANSWER:

BHC and BII admit that heparin can be a pork-derived product and that it has been used since the at least the early 1990s. BHC and BII admit that heparin is one of the oldest drugs currently still in widespread clinical use.

13. Heparin works by decreasing the clotting ability of the blood, thereby preventing the actual formation of clots or preventing the extension of existing clots within the blood.

ANSWER:

BHC and BII admit the allegations of Paragraph 13, Count II of the Complaint.

14. It is most often administered intravenously and is used primarily to decrease the chance of clots forming in patients undergoing certain medical procedures such as cardiac surgery, in preventing the formation of clots in catheters (small plastic tubes through which medication is administered or blood drawn) such as in kidney dialysis, and for other such conditions like pulmonary emboli.

ANSWER:

BHC and BII admit the allegations in Paragraph 14, Count II of the Complaint but note that heparin is also administered subcutaneously and for other medical purposes.

15. The Food and Drug Administration ("FDA") estimates that more than 1 million multiple-dose vials are sold each month in the United States.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 15, Count II of the Complaint and, therefore, deny the same.

16. Baxter is one of the largest producers of Heparin in the United States, and its sales of heparin constitute at least a 50% market share.

ANSWER:

BHC and BII admit that Baxter Healthcare Corporation is one of the largest producers of heparin in the United States and that Baxter supplies approximately half of the multi-dose vials of heparin used in the United States. BHC and BII deny the remaining allegations of Paragraph 16, Count II of the Complaint.

17. Baxter sells an estimated 35 million units of Heparin per year, with annual sales of approximately $30 million dollars.

ANSWER:

BHC and BII admit that Baxter Healthcare Corporation sells approximately 35 million units of heparin sodium injection multi and single dose vials per year in the United States, with an annual sales value of approximately $30 million.

18. Baxter reported total sales in the amount of $11.3 billion dollars for 2007, with over 70% of its revenues being sourced form products in market-leading positions.

ANSWER:

BHC and BII admits that Baxter International Inc. reported net sales of $11.3 billion for 2007. BHC and BII deny the remaining allegations of Paragraph 18, Count II of the Complaint.

19. The multiple-dose heparin vials were represented by Defendants to be safe and effective for their intended uses, including, but not limited to, intravenous administration during hemodialysis.

ANSWER:

BHC and BII provided written labels and warnings with its multiple-dose heparin vials as required by law that speak for themselves. BHC and BII deny the remaining allegations of Paragraph 19, Count II of the Complaint.

20. The multiple-dose heparin vials were defective in their manufacture.

ANSWER:

BHC and BII deny the allegations of Paragraph 20, Count II of the Complaint.

21. Defendants are designers, developers, manufacturers, wholesales, retailers, fabricators, suppliers and/or distributors of the multiple-dose heparin vials, one or more of which was administered to Paul Hills during a hemodialysis session or sessions.

ANSWER:

BHC and BII admit that they manufacture and supply multiple-dose heparin vials. BHC and BII deny that they are designers, developers, wholesalers, retailers or distributors of heparin. BHC and BII are without knowledge or information sufficient to form a belief as to the allegation that heparin from their multiple dose vials was administered to Plaintiff and, therefore, deny the same.

22. The multiple-dose heparin vials were manufactured, fabricated, distributed, supplied and/or placed in the stream of interstate commerce by Defendants.

ANSWER:

BHC and BII admit that they manufacture and supply multiple-dose heparin vials. BHC and BII deny the remaining allegations of Paragraph 22, Count II of the Complaint.

23. Defendants obtained the component parts for the multiple-dose heparin vials from unidentified supply companies, including, but not limited to, Scientific Protein Laboratories, who has two plants which supply the active pharmaceutical ingredient for heparin to Defendants.

ANSWER:

BHC and BII admit that they obtained the active pharmaceutical ingredient (API) for its multiple-dose heparin vials from Scientific Protein Laboratories. BHC and BII deny that they obtained heparin API from any "unidentified" or "unknown" supply companies. BHC and BII are without information or knowledge sufficient to form a belief as to the remaining allegations of Paragraph 23, Count II of the Complaint and, therefore, deny the same.

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ANSWER:

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25. One of these plants is located in China and upon information belief, has not met the requisite requirements for importation and/or sale within the United States.

ANSWER:

BHC and BII deny the allegations of Paragraph 25, Count II of the Complaint

26. Such requirements include, but are not necessarily limited to, inspection and approval by the Food and Drug Administration as is required for any facility to supple [sic] drug ingredients to the United States.

ANSWER:

Paragraph 26, Count II of the Complaint contains legal conclusions to which BHC and BII do not believe a response is due. To the extent that response is required, BHC and BII deny the allegations of Paragraph 26, Count II of the Complaint.

27. Upon information and belief, Defendants knew or should have known of such noncompliance or lack of plant inspection and/or approval, which is required for all foreign facilities.

ANSWER:

BHC and BII deny the allegations of Paragraph 27, Count II of the Complaint.

28. Such multiple-dose heparin vials were defective at the time they were placed in the stream of commerce.

ANSWER:

BHC and BII deny the allegations of Paragraph 28, Count II of the Complaint.

29. Baxter knew or should have known that these multiple-dose heparin vials were defective at the time they left Baxter's control and custody.

ANSWER:

BHC and BII deny the allegations of Paragraph 29, Count II of the Complaint.

30. Defendants also knew or should have known that the multiple-dose heparin vials were causing adverse reactions for patients, such as Paul Hills.

ANSWER:

BHC and BII deny the allegations of Paragraph 30, Count II of the Complaint.

31. Notwithstanding their knowledge, Baxter continued to supply and sell the multiple-dose heparin vials up to and until just recently, without providing any warnings about the risks and drugs associated with the multiple-dose heparin vials to members of the public and the medical community, including Paul Hills.

ANSWER:

BHC and BII deny the allegations of Paragraph 31, Count II of the Complaint.

32. At all material times, Baxter intentionally concealed from the public and members of the medical community, including Paul Hills, the risks and dangers associated with the use of the multiple-dose heparin vials, and/or has misrepresented the safety, quality and performance of multiple-dose heparin vials.

ANSWER:

BHC and BII deny the allegations of Paragraph 32, Count II of the Complaint.

33. On or about January 17, 2008, Baxter and the FDA both issued press releases regarding the voluntary recall by Baxter of nine lots of Heparin Sodium Injection multiple dose vials in 1000 units/mL concentrations of 10mL and 30mL vials, 5000 units/mL concentration of 10 mL vials and 10,000 units for 4mL vials.

ANSWER:

BHC and BII admit that on or about January 25, 2008, Baxter Healthcare Corporation issued a press release discussing the voluntary recall of nine lots of heparin sodium injection 1000 units/mL 10mL and 30mL multi-dose vials as a precautionary measure. BHC and BII deny the remaining allegations of Paragraph 33, Count II of the Complaint.

34. This voluntary recall was the result of an abnormal increase in the reports of adverse patient reactions associated with the use of heparin.

ANSWER:

BHC and BII admit that Baxter Healthcare Corporation initiated the voluntary recall as a precautionary measure due to an increase in the number of reports of adverse patient reactions

that may be associated with the use of heparin. BHC and BII deny the remaining allegations of Paragraph 34, Count II of the Complaint.

35. These adverse patient reactions included the following: allergic or hypersensitivity-type reactions, with symptoms of oral swelling, abdominal pains, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, and unresponsiveness to stimul [sic], as well as cases of severe hypotension requiring treatment.

ANSWER:

BHC and BII admit that reported adverse patient reactions included oral swelling, abdominal pains, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, hypotension, and unresponsiveness to stimuli. BHC and BII deny the remaining allegations of Paragraph 35, Count II of the Complaint.

36. These adverse reports began as early as November 19, 2007, from more than nineteen dialysis facilities in more than twelve states.

ANSWER:

BHC and BII deny the allegations of Paragraph 36, Count II of the Complaint.

37. An estimated 40% of the adverse reports have been categorized as serious by the FDA and there have been at least four reported deaths.

ANSWER:

BHC and BII admit that at least four deaths have been reported but deny a causal relationship between the allergic reactions involved in the heparin recall and the four fatalities. BHC and BII deny the remaining allegations of Paragraph 37, Count II of the Complaint.

38. The bulk of the adverse reports have centered on adverse events occurring at hemodialysis centers.

ANSWER:

BHC and BII deny allegations of Paragraph 38, Count II of the Complaint.

39. According to the FDA, there has been a significant increase in reported adverse events associated with the use of Heparin, with an estimated 350 events reported since December 2007 in contrast to less then 100 reports in 2007.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 39, Count II of the Complaint and, therefore, deny the same.

40. Based upon the clusters of adverse reports, Baxter and the Center for Disease Control ("CDC") initially identified nine specific Heparin manufacturing lots with a suggested link to those cases.

ANSWER:

BHC and BII admit the allegations of Paragraph 40, Count II of the Complaint.

41. The initial nine lots recalled by Baxter ware [sic] for the following Heparin products: NDC#00641-2440-45, NDC#00641-2440-41, NDC#00641-2450-45, and NDC#00641-2450-41. The products include the following lots:

a. Heparin 1000 units/mL, 10mL vial, expiration date 10/2009, Lot #107054
b. Heparin 1000 units/mL, 10 mL vial, expiration date 11/2009, Lot #117085
c. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2008, Lot #047056
d. Heparin 1000 units/mL, 30 mL vial, expiration date 9/2009, Lot #097081
e. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2009, Lot #107024
f. Heparin 1000 units/mL, 30mL vial, expiration date 10/2009, Lot #107064
g. Heparin 1000 units/mL, 30mL, expiration date 10/2009, Lot #107066
h. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107074
i. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107111

ANSWER:

BHC and BII admit the allegations of Paragraph 41, Count II of the Complaint.

42. Upon information and belief, these nine lots were all manufactured at a single facility between September and November of 207 [sic].

ANSWER:

BHC and BII admit that the nine lots listed in Paragraph 41 were manufactured at Baxter Healthcare Corporation's Cherry Hill facility. BHC and BII deny the remaining allegations of Paragraph 42, Count II of the Complaint.

43. Upon information and belief, the active pharmaceutical ingredient in these products was at least in part provided by a third party supplier from an unapproved facility in China.

ANSWER:

BHC and BII deny the allegations of Paragraph 43, Count II of the Complaint.

44. However, according to FDA updates, more recent information indicates that comparable adverse events are continuing to be reported that are associated with the use of multiple-dose heparin vials of different manufacturing lots than those identified in the initial voluntary recall.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 44, Count II of the Complaint and, therefore, deny the same.

45. The FDA began inspections of Baxter's manufacturing plant in Cherry Hill, New Jersey and its processes on or about January 16, 2008.

ANSWER:

BHC and BII admit the allegations of Paragraph 45, Count II of the Complaint.

46. The FDA and CDC are continuing with an investigation to discover the underlying cause of these anomalous adverse events.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 46, Count II of the Complaint and, therefore, deny the same.

47. As of February 11, 2008, Baxter ceased production of all of its multiple-dose vials of injectible heparin due to the potentially life threatening adverse and allergic reactions and incidents of hypotension that are being reported.

ANSWER:

BHC and BII deny the allegations of Paragraph 47, Count II of the Complaint.

Paul Hills

48. On or about July 24, 2007, Paul Hills had a surgical procedure performed for an abdominal aneurysm at Evanston Hospital in Evanston, IL.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 48, Count II of the Complaint and, therefore, deny the same.

49. On or about July 24, 2007, the aforesaid procedure performed on Paul Hills was successful and he was expected at that point in time to have a complete and full recovery.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 49, Count II of the Complaint and, therefore, deny the same.

50. On or about July 24, 2007, Paul Hills was administered the aforesaid contaminated Heparin manufactured by Baxter.

ANSWER:

The allegations of Paragraph 50, Count II of the Complaint are vague and ambiguous. To the extent that a response is required, BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 50, Count II of the Complaint and, therefore, deny the same.

51. Following the July 24, 2007 procedure, Paul Hills manifested signs and symptoms consistent with the administration of contaminated heparin including: dizziness, fainting, stomach pain and a fast heart rate.

ANSWER:

The allegations of Paragraph 51, Count II of the Complaint are vague and ambiguous. To the extent that a response is required, BHC and BII are without knowledge or information

sufficient to form a belief as to the truth of the allegations of Paragraph 51, Count II of the Complaint and, therefore, deny the same.

52. On and after July 24, 2007, Paul Hills had an extensive hospitalization due to complications from the contaminated heparin.

ANSWER:

The allegations of Paragraph 52, Count II of the Complaint are vague and ambiguous. To the extent that a response is required, BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 52, Count II of the Complaint and, therefore, deny the same.

53. On or prior to July 24, 2007, Baxter Healthcare manufactured and distributed the aforesaid contaminated Heparin product which was unreasonably dangerous for its intended use and was defective.

ANSWER:

BHC and BII deny the allegations of Paragraph 53, Count II of the Complaint.

54. Prior to July 24, 2007, the aforesaid contaminated Heparin was introduced into the stream of commerce by Baxter Healthcare and/or Baxter International.

ANSWER:

BHC and BII deny the allegations of Paragraph 54, Count II of the Complaint.

55. Prior to July 24, 2007, and at the time Baxter Healthcare and/or Baxter International introduced the aforementioned contaminated heparin into the stream of commerce the heparin contained a material defect.

ANSWER:

BHC and BII deny the allegations of Paragraph 55, Count II of the Complaint.

56. On July 24, 2007 and at the time the contaminated heparin was administered to Paul Hills, the heparin failed to perform in the manner reasonably to be expected.

ANSWER:

The allegations of Paragraph 56, Count II of the Complaint are vague and ambiguous. To the extent that a response is required, BHC and BII are without knowledge or information

sufficient to form a belief as to the truth of the allegations of Paragraph 56, Count II of the Complaint and, therefore, deny the same.

57. Prior to July 24, 2007, Baxter Healthcare and/or Baxter International failed to adequately warn of the danger of the contamination in the aforementioned contaminated heparin.

ANSWER:

BHC and BII deny the allegations of Paragraph 57, Count II of the Complaint.

58. As a direct and proximate result of Defendants' defective multiple-dose heparin vials, Paul Hills has been injured and incurred substantial damages, including, but not limited to, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

ANSWER:

BHC and BII deny the allegations of Paragraph 58, Count II of the Complaint.

WHEREFORE, plaintiff, PAUL HILLS, by his attorneys, POWER ROGERS & SMITH, demands judgment against Defendant, PROTEIN SCIENTIFIC LABORATORIES [sic], in such sum of money in excess of FIFTY THOUSAND DOLLARS ($50,000.00) as shall represent fair and just compensation.

ANSWER:

BHC and BII deny that Plaintiff is entitled to the relief sought in the final Paragraph of Count II of the Complaint, or any relief whatsoever from BHC and BII.

COUNT III
BAXTER HEALTHCARE AND BAXTER INTERNATIONAL INC.
(WRONGFUL DEATH-NEGLIGENCE)

1. Plaintiff, Paul Hills, was at all relevant times a resident of Evanston, Illinois, Cook County.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1, Count III of the Complaint and, therefore, deny the same.

2. Defendant, Baxter Healthcare Corporation has its principle [sic] place of business at One Baxter Parkway in Deerfield, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 2, Count III of the Complaint.

3. Defendant, Baxter International Inc. has its principle [sic] place of business at One Baxter Parkway in Deerfield, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 3, Count III of the Complaint.

4. At all relevant times, the registered agent for Baxter Healthcare Corporation was CT Corporation located in Cook County, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 4, Count III of the Complaint.

5. At all relevant times, the registered agent for Baxter International was CT Corporation located in Cook County, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 5, Count III of the Complaint.

6. Scientific Protein Laboratories is a corporation which produces ingredients for intravenous heparin. Scientific Protein Laboratories has its principle [sic] place of business in Waunakee, Wisconsin.

ANSWER:

Upon information and belief, BHC and BII admit the allegations of Paragraph 6, Count III of the Complaint.

7. At all relevant times, Baxter Healthcare Corporation was in the business of designing, manufacturing and distributing intravenous Heparin for profit.

ANSWER:

BHC and BII deny the allegation that Baxter Healthcare Corporation designs, has designed or was "in the business of designing" intravenous heparin. BHC and BII admit the remaining allegation in Paragraph 7, Count III of the Complaint.

8. At all relevant times, Baxter Healthcare Corporation marketed and advertised is [sic] pharmaceutical sales within Cook County.

ANSWER:

BHC and BII admit the allegations of Paragraph 8, Count III of the Complaint.

9. At all relevant times, Baxter Healthcare Corporation employed a number of employees that worked within Cook County, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 9, Count III of the Complaint.

10. At all relevant times, Baxter Healthcare Corporation sold millions of dollars worth of pharmaceutical products including intravenous Heparin to healthcare providers in Cook County, Illinois.

ANSWER:

BHC and BII deny the allegations of Paragraph 10, Count III of the Complaint.

Contaminated Heparin

11. Heparin is a prescription drug in a class of medications called anti-coagulants also known as blood thinners.

ANSWER:

BHC and BII admit that heparin is an anticoagulant, also known as a blood thinner. BHC and BII admit that heparin is classed for regulatory purposes as a prescription drug, although heparin is in reality a complex biologic.

12. Heparin is a pork-derived product and one of the oldest drugs currently still in widespread clinical use, having been used since the early 1990s.

ANSWER:

BHC and BII admit that heparin can be a pork-derived product and that it has been used since the at least the early 1990s. BHC and BII admit that heparin is one of the oldest drugs currently still in widespread clinical use.

13. Heparin works by decreasing the clotting ability of the blood, thereby preventing the actual formation of clots or preventing the extension of existing clots within the blood.

ANSWER:

BHC and BII admit the allegations of Paragraph 13, Count III of the Complaint.

14. It is most often administered intravenously and is used primarily to decrease the chance of clots forming in patients undergoing certain medical procedures such as cardiac surgery, in preventing the formation of clots in catheters (small plastic tubes through which medication is administered or blood drawn) such as in kidney dialysis, and for other such conditions like pulmonary emboli.

ANSWER:

BHC and BII admit the allegations in Paragraph 14, Count III of the Complaint but note that heparin is also administered subcutaneously and for other medical purposes.

15. The Food and Drug Administration ("FDA") estimates that more than 1 million multiple-dose vials are sold each month in the United States.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 15, Count III of the Complaint and, therefore, deny the same.

16. Baxter is one of the largest producers of Heparin in the United States, and its sales of heparin constitute at least a 50% market share.

ANSWER:

BHC and BII admit that Baxter Healthcare Corporation is one of the largest producers of heparin in the United States and that Baxter supplies approximately half of the multi-dose vials of heparin used in the United States. BHC and BII deny the remaining allegations of Paragraph 16, Count III of the Complaint.

17. Baxter sells an estimated 35 million units of Heparin per year, with annual sales of approximately $30 million dollars.

ANSWER:

BHC and BII admit that Baxter Healthcare Corporation sells approximately 35 million units of heparin sodium injection multi and single dose vials per year in the United States, with an annual sales value of approximately $30 million.

18. Baxter reported total sales in the amount of $11.3 billion dollars for 2007, with over 70% of its revenues being sourced form products in market-leading positions.

ANSWER:

BHC and BII admits that Baxter International Inc. reported net sales of $11.3 billion for 2007. BHC and BII deny the remaining allegations of Paragraph 18, Count III of the Complaint.

19. The multiple-dose heparin vials were represented by Defendants to be safe and effective for their intended uses, including, but not limited to, intravenous administration during hemodialysis.

ANSWER:

BHC and BII provided written labels and warnings with its multiple-dose heparin vials as required by law that speak for themselves. BHC and BII deny the remaining allegations of Paragraph 19, Count III of the Complaint.

20. The multiple-dose heparin vials were defective in their manufacture.

ANSWER:

BHC and BII deny the allegations of Paragraph 20, Count III of the Complaint.

21. Defendants are designers, developers, manufacturers, wholesales, retailers, fabricators, suppliers and/or distributors of the multiple-dose heparin vials, one or more of which was administered to the Paul Hills during a hemodialysis session or sessions.

ANSWER:

BHC and BII admit that they manufacture and supply multiple-dose heparin vials. BHC and BII deny that they are designers, developers, wholesalers, retailers or distributors of heparin. BHC and BII are without knowledge or information sufficient to form a belief as to the

allegation that heparin from their multiple-dose vials was administered to Plaintiff and, therefore, deny the same.

22. The multiple-dose heparin vials were manufactured, fabricated, distributed, supplied and/or placed in the stream of interstate commerce by Defendants.

ANSWER:

BHC and BII admit that they manufacture and supply multiple-dose heparin vials. BHC and BII deny the remaining allegations of Paragraph 22, Count III of the Complaint.

23. Defendants obtained the component parts for the multiple-dose heparin vials from unidentified supply companies, including, but not limited to, Scientific Protein Laboratories, who has two plants which supply the active pharmaceutical ingredient for heparin to Defendants.

ANSWER:

BHC and BII admit that they obtained the active pharmaceutical ingredient (API) for its multiple-dose heparin vials from Scientific Protein Laboratories. BHC and BII deny that they obtained heparin API from any "unidentified" or "unknown" supply companies. BHC and BII are without information or knowledge sufficient to form a belief as to the remaining allegations of Paragraph 23, Count III of the Complaint and, therefore, deny the same.

24. The active pharmaceutical ingredient in heparin is an enzyme that is extracted from pig intestines.

ANSWER:

BHC and BII admit the allegations of Paragraph 24, Count III of the Complaint.

25. One of these plants is located in China and upon information belief, has not met the requisite requirements for importation and/or sale within the United States.

ANSWER:

BHC and BII deny the allegations of Paragraph 25, Count III of the Complaint.

26. Such requirements include, but are not necessarily limited to, inspection and approval by the Food and Drug Administration as is required for any facility to supple [sic] drug ingredients to the United States.

ANSWER:

Paragraph 26, Count III of the Complaint contains legal conclusions to which BHC and BII do not believe a response is due. To the extent that response is required, BHC and BII deny the allegations of Paragraph 26, Count III of the Complaint.

27. Upon information and belief, Defendants knew or should have known of such noncompliance or lack of plant inspection and/or approval, which is required for all foreign facilities.

ANSWER:

BHC and BII deny the allegations of Paragraph 27, Count III of the Complaint.

28. Such multiple-dose heparin vials were defective at the time they were placed in the stream of commerce.

ANSWER:

BHC and BII deny the allegations of Paragraph 28, Count III of the Complaint.

29. Baxter knew or should have known that these multiple-dose heparin vials were defective at the time they left Baxter's control and custody.

ANSWER:

BHC and BII deny the allegations of Paragraph 29, Count III of the Complaint.

30. Defendants also knew or should have known that the multiple-dose heparin vials were causing adverse reactions for patients, such as Paul Hills.

ANSWER:

BHC and BII deny the allegations of Paragraph 30, Count III of the Complaint.

31. Notwithstanding their knowledge, Baxter continued to supply and sell the multiple-dose heparin vials up to and until just recently, without providing any warnings about the risks and drugs associated with the multiple-dose heparin vials to members of the public and the medical community, including Paul Hills.

ANSWER:

BHC and BII deny the allegations of Paragraph 31, Count III of the Complaint.

32. At all material times, Baxter intentionally concealed from the public and members of the medical community, including Paul Hills, the risks and dangers associated with the use of

the multiple-dose heparin vials, and/or has misrepresented the safety, quality and performance of multiple-dose heparin vials.

ANSWER:

BHC and BII deny the allegations of Paragraph 32, Count III of the Complaint.

33. On or about January 17, 2008, Baxter and the FDA both issued press releases regarding the voluntary recall by Baxter of nine lots of Heparin Sodium Injection multiple dose vials in 1000 units/mL concentrations of 10mL and 30mL vials, 5000 units/mL concentration of 10mL vials and 10,000 units for 4mL vials.

ANSWER:

BHC and BII admit that on or about January 25, 2008, Baxter Healthcare Corporation issued a press release discussing the voluntary recall of nine lots of heparin sodium injection 1000 units/mL 10mL and 30mL multi-dose vials as a precautionary measure. BHC and BII deny the remaining allegations of Paragraph 33, Count III of the Complaint.

34. This voluntary recall was the result of an abnormal increase in the reports of adverse patient reactions associated with the use of heparin.

ANSWER:

BHC and BII admit that Baxter Healthcare Corporation initiated the voluntary recall as a precautionary measure due to an increase in the number of reports of adverse patient reactions that may be associated with the use of heparin. BHC and BII deny the remaining allegations of Paragraph 34, Count III of the Complaint.

35. These adverse patient reactions included the following: allergic or hypersensitivity-type reactions, with symptoms of oral swelling, abdominal pains, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, and unresponsiveness to stimul [sic], as well as cases of severe hypotension requiring treatment.

ANSWER:

BHC and BII admit that reported adverse patient reactions included oral swelling, abdominal pains, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, hypotension, and unresponsiveness to stimuli. BHC and BII deny the remaining allegations of Paragraph 35, Count III of the Complaint.

36. These adverse reports began as early as November 19, 2007, from more than nineteen dialysis facilities in more than twelve states.

ANSWER:

BHC and BII deny the allegations of Paragraph 36, Count III of the Complaint.

37. An estimated 40% of the adverse reports have been categorized as serious by the FDA and there have been at least four reported deaths.

ANSWER:

BHC and BII admit that at least four deaths have been reported but deny a causal relationship between the allergic reactions involved in the heparin recall and the four fatalities. BHC and BII deny the remaining allegations of Paragraph 37, Count III of the Complaint.

38. The bulk of the adverse reports have centered on adverse events occurring at hemodialysis centers.

ANSWER:

BHC and BII deny the allegations of Paragraph 38, Count III of the Complaint.

39. According to the FDA, there has been a significant increase in reported adverse events associated with the use of Heparin, with an estimated 350 events reported since December 2007 in contrast to less then 100 reports in 2007.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 39, Count III of the Complaint and, therefore, deny the same.

40. Based upon the clusters of adverse reports, Baxter and the Center for Disease Control ("CDC") initially identified nine specific Heparin manufacturing lots with a suggested link to those cases.

ANSWER:

BHC and BII admit the allegations of Paragraph 40, Count III of the Complaint.

41. The initial nine lots recalled by Baxter ware [sic] for the following Heparin products: NDC#00641-2440-45, NDC#00641-2440-41, NDC#00641-2450-45, and NDC#00641-2450-41. The products include the following lots:

a. Heparin 1000 units/mL, 10mL vial, expiration date 10/2009, Lot #107054
b. Heparin 1000 units/mL, 10 mL vial, expiration date 11/2009, Lot #117085
c. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2008, Lot #047056
d. Heparin 1000 units/mL, 30 mL vial, expiration date 9/2009, Lot #097081
e. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2009, Lot #107024
f. Heparin 1000 units/mL, 30mL vial, expiration date 10/2009, Lot #107064
g. Heparin 1000 units/mL, 30mL, expiration date 10/2009, Lot #107066
h. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107074
i. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107111

ANSWER:

BHC and BII admit the allegations of Paragraph 41, Count III of the Complaint.

42. Upon information and belief, these nine lots were all manufactured at a single facility between September and November of 207 [sic].

ANSWER:

BHC and BII admit that the nine lots listed in Paragraph 41 were manufactured at Baxter Healthcare Corporation's Cherry Hill facility. BHC and BII deny the remaining allegations of Paragraph 42, Count III of the Complaint.

43. Upon information and belief, the active pharmaceutical ingredient in these products was at least in part provided by a third party supplier from an unapproved facility in China.

ANSWER:

BHC and BII deny the allegations of Paragraph 43, Count III of the Complaint.

44. However, according to FDA updates, more recent information indicates that comparable adverse events are continuing to be reported that are associated with the use of multiple-dose heparin vials of different manufacturing lots than those identified in the initial voluntary recall.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 44, Count III of the Complaint and, therefore, deny the same.

45. The FDA began inspections of Baxter's manufacturing plant in Cherry Hill, New Jersey and its processes on or about January 16, 2008.

ANSWER:

BHC and BII admit the allegations of Paragraph 45, Count III of the Complaint.

46. The FDA and CDC are continuing with an investigation to discover the underlying cause of these anomalous adverse events.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 46, Count III of the Complaint and, therefore, deny the same.

47. As of February 11, 2008, Baxter ceased production of all of its multiple-dose vials of injectible heparin due to the potentially life threatening adverse and allergic reactions and incidents of hypotension that are being reported.

ANSWER:

BHC and BII deny the allegations of Paragraph 47, Count III of the Complaint.

Paul Hills

48. On or about July 24, 2007, Paul Hills had a surgical procedure performed for an abdominal aortic aneurysm at Evanston Hospital in Evanston, IL.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 48, Count III of the Complaint and, therefore, deny the same.

49. On or about July 24, 2007, the aforesaid procedure performed on Paul Hills was successful and he was expected at that point in time to have a complete and full recovery.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 49, Count III of the Complaint and, therefore, deny the same.

50. On or about July 24, 2007, Paul Hills was administered the aforesaid contaminated Heparin manufactured by Baxter.

ANSWER:

The allegations of Paragraph 50, Count III of the Complaint are vague and ambiguous. To the extent that a response is required, BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 50, Count III of the Complaint and, therefore, deny the same.

51. Following the July 24, 2007 procedure, Paul Hills manifested signs and symptoms consistent with the administration of contaminated heparin including: dizziness, fainting, stomach pain and a fast heart rate.

ANSWER:

The allegations of Paragraph 51, Count III of the Complaint are vague and ambiguous. To the extent that a response is required, BHC and BII are without knowledge or information

sufficient to form a belief as to the truth of the allegations of Paragraph 51, Count III of the Complaint and, therefore, deny the same.

52. On and after July 24, 2007, Paul Hills had an extensive hospitalization due to complications from the contaminated heparin.

ANSWER:

The allegations of Paragraph 52, Count III of the Complaint are vague and ambiguous. To the extent that a response is required, BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 52, Count III of the Complaint and, therefore, deny the same.

53. On and prior to July 24, 2007, Baxter Healthcare manufactured and distributed the aforesaid contaminated Heparin product which was unreasonably dangerous for its intended use and was defective.

ANSWER:

Paragraph 53, Count III of the Complaint contains legal conclusions to which BHC and BII do not believe a response is due. To the extent a response is required, BHC and BII deny the allegations of Paragraph 53, Count III of the Complaint.

54. Baxter owed a duty to exercise reasonable care in the design, manufacture, testing, marketing, distributing, sale, and/or post-sale surveillance of these products, including the dose given to Paul Hills, so that it could be safely used for the purpose for which it was intended, or in a reasonable foreseeable manner.

ANSWER:

Paragraph 54, Count III of the Complaint contains legal conclusions to which BHC and BII do not believe a response is due. To the extent a response is required, BHC and BII deny the allegations of Paragraph 54, Count III of the Complaint.

55. This duty included the duty not to introduce a dangerous and unfit pharmaceutical drug, such as the multiple-dose heparin vials, into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects, up to and including death.

ANSWER:

Paragraph 55, Count III of the Complaint contains legal conclusions to which BHC and BII do not believe a response is due. To the extent a response is required, BHC and BII deny the allegations of Paragraph 55, Count III of the Complaint.

56. In breach of their duty of care, Baxter was negligent in the manufacturer, testing, distribution, marketing, sale, and/or post-sale surveillance of the multiple-dose heparin vials, including as follows:

a. Baxter failed to exercise reasonable care in the manufacture of their multiple-dose heparin vials;

b. Baxter failed to exercise reasonable care in the inspection of their multiple-dose heparin vials;

c. Baxter failed to exercise reasonable care in the packaging of their multiple-dose heparin vials;

d. Baxter failed to provide any and adequate warnings about the risks and dangers associated with the use of their multiple-dose heparin vials, as alleged herein;

e. Baxter failed to completely, accurately and in a timely fashion, disclose the adverse events reports associated with the use of its multiple-dose heparin vials;

f. Baxter failed to recall, withdraw, and remove their multiple-dose heparin vials from the market once they knew or should have known of the risks and dangers associated with the use thereof;

g. Baxter failed to promptly respond to data, reports, and publications describing problems associated with their multiple-dose heparin vials by conducting adequate analysis, testing, and surveillance;

h. Baxter failed to implement pre-marketing and post-marketing measures to notify and warn Paul Hills, as well as his physicians, medical providers, and other members of the medical community, of the risks and dangers associated with the use of the said multiple-dose heparin vials, and to recall the defective multiple-dose heparin vials;

i. Baxter failed to adequately and reasonably establish, maintain and comport with acceptable quality control mechanisms to prevent defective products from entering the marketplace or from using unsafe ingredients;

j. Baxter failed to adequately and reasonably ensure quality controls were in the place and as such controls were adhered to obtaining the component parts for the multiple-dose heparin vials, including, but not limited to, the active pharmaceutical ingredient;

k. Baxter failed to adequately and reasonably ensure compliance with all applicable laws, regulations, and administrative approval or licensing requirements;

1. Baxter failed to adequately monitor and/or take reasonable precautions to ensure that the active pharmaceutical ingredients in heparin were of suitable quality and safety; and

m. Baxter was otherwise negligent and careless.

ANSWER:

BHC and BII deny the allegations of Paragraph 56, Count III of the Complaint including all allegations in subparts 56 (a-m).

57. Baxter knew or should have known that patients/consumers such as Paul Hills Sean Valenzo [sic] would foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.

ANSWER:

BHC and BII deny the allegations of Paragraph 57, Count III of the Complaint.

58. Baxter's multiple-dose heparin vials were expected to and did reach Paul Hills without substantial change in the condition as designed, manufactured, marketed, distributed, and sold, prior to their administration to Paul Hills, who used the heparin as intended, or in a reasonably foreseeable manner.

ANSWER:

BHC and BII deny the allegations of Paragraph 58, Count III of the Complaint.

59. Baxter's negligent conduct caused substantial harm to Paul Hills.

ANSWER:

BHC and BII deny the allegations of Paragraph 59, Count III of the Complaint.

60. As a direct and proximate result of Defendants' defective multiple-dose heparin vials, Paul Hills has been injured and incurred substantial damages, including, but not limited to, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

ANSWER:

BHC and BII deny the allegations of Paragraph 59, Count III of the Complaint.

WHEREFORE, plaintiff, PAUL HILLS, by his attorneys, POWER ROGERS & SMITH, demands judgment against Defendant, BAXTER HEALTHCARE and/or BAXTER INTERNATIONAL INC., in such sum of money in excess of FIFTY THOUSAND DOLLARS ($50,000.00) as shall represent fair and just compensation.

ANSWER:

BHC and BII deny that Plaintiff is entitled to the relief sought in the final Paragraph of Count III of the Complaint, or any relief whatsoever from BHC and BII.

COUNT IV
SCIENTIFIC PROTEIN LABORATORIES
(WRONGFUL DEATH-NEGLIGENCE)

1. Plaintiff, Paul Hills, was at all relevant times a resident of Evanston, Illinois, Cook County.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1, Count IV of the Complaint and, therefore, deny the same.

2. Defendant, Baxter Healthcare Corporation has its principle [sic] place of business at One Baxter Parkway in Deerfield, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 2, Count IV of the Complaint.

3. Defendant, Baxter International Inc. has its principle [sic] place of business at One Baxter Parkway in Deerfield, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 3, Count IV of the Complaint.

4. At all relevant times, the registered agent for Baxter Healthcare Corporation was CT Corporation located in Cook County, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 4, Count IV of the Complaint.

5. At all relevant times, the registered agent for Baxter International was CT Corporation located in Cook County, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 5, Count IV of the Complaint.

6. Scientific Protein Laboratories is a corporation which produces ingredients for intravenous heparin. Scientific Protein Laboratories has its principle [sic] place of business in Waunakee, Wisconsin.

ANSWER:

Upon information and belief, BHC and BII admit the allegations of Paragraph 6, Count IV of the Complaint.

7. At all relevant times, Baxter Healthcare Corporation was in the business of designing, manufacturing and distributing intravenous Heparin for profit.

ANSWER:

BHC and BII deny the allegation that Baxter Healthcare Corporation designs, has designed or was "in the business of designing" intravenous heparin. BHC and BII admit the remaining allegation in Paragraph 7, Count IV of the Complaint.

8. At all relevant times, Baxter Healthcare Corporation marketed and advertised is [sic] pharmaceutical sales within Cook County.

ANSWER:

BHC and BII admit the allegations of Paragraph 8, Count IV of the Complaint.

9. At all relevant times, Baxter Healthcare Corporation employed a number of employees that worked within Cook County, Illinois.

ANSWER:

BHC and BII admit the allegations of Paragraph 9, Count IV of the Complaint.

10. At all relevant times, Baxter Healthcare Corporation sold millions of dollars worth of pharmaceutical products including intravenous Heparin to healthcare providers in Cook County, Illinois.

ANSWER:

BHC and BII deny the allegations of Paragraph 10, Count IV of the Complaint.

Contaminated Heparin

11. Heparin is a prescription drug in a class of medications called anti-coagulants also known as blood thinners.

ANSWER:

BHC and BII admit that heparin is an anticoagulant, also known as a blood thinner. BHC and BII admit that heparin is classed for regulatory purposes as a prescription drug, although heparin is in reality a complex biologic.

12. Heparin is a pork-derived product and one of the oldest drugs currently still in widespread clinical use, having been used since the early 1990s.

ANSWER:

BHC and BII admit that heparin can be a pork-derived product and that it has been used since the at least the early 1990s. BHC and BII admit that heparin is one of the oldest drugs currently still in widespread clinical use.

13. Heparin works by decreasing the clotting ability of the blood, thereby preventing the actual formation of clots or preventing the extension of existing clots within the blood.

ANSWER:

BHC and BII admit the allegations of Paragraph 13, Count IV of the Complaint.

14. It is most often administered intravenously and is used primarily to decrease the chance of clots forming in patients undergoing certain medical procedures such as cardiac surgery, in preventing the formation of clots in catheters (small plastic tubes through which medication is administered or blood drawn) such as in kidney dialysis, and for other such conditions like pulmonary emboli.

ANSWER:

BHC and BII admit the allegations in Paragraph 14, Count IV of the Complaint but note that heparin is also administered subcutaneously and for other medical purposes.

15. The Food and Drug Administration ("FDA") estimates that more than 1 million multiple-dose vials are sold each month in the United States.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 15, Count IV of the Complaint and, therefore, deny the same.

16. Baxter is one of the largest producers of Heparin in the United States, and its sales of heparin constitute at least a 50% market share.

ANSWER:

BHC and BII admit that Baxter Healthcare Corporation is one of the largest producers of heparin in the United States and that Baxter supplies approximately half of the multi-dose vials of heparin used in the United States. BHC and BII deny the remaining allegations of Paragraph 16, Count IV of the Complaint.

17. Baxter sells an estimated 35 million units of Heparin per year, with annual sales of approximately $30 million dollars.

ANSWER:

BHC and BII admit that Baxter Healthcare Corporation sells approximately 35 million units of heparin sodium injection multi and single dose vials per year in the United States, with an annual sales value of approximately $30 million.

18. Baxter reported total sales in the amount of $11.3 billion dollars for 2007, with over 70% of its revenues being sourced form products in market-leading positions.

ANSWER:

BHC and BII admits that Baxter International Inc. reported net sales of $11.3 billion for 2007. BHC and BII deny the remaining allegations of Paragraph 18, Count IV of the Complaint.

19. The multiple-dose heparin vials were represented by Defendants to be safe and effective for their intended uses, including, but not limited to, intravenous administration during hemodialysis.

ANSWER:

BHC and BII provided written labels and warnings with its multiple-dose heparin vials as required by law that speak for themselves. BHC and BII deny the remaining allegations of Paragraph 19, Count IV of the Complaint.

20. The multiple-dose heparin vials were defective in their manufacture.

ANSWER:

BHC and BII deny the allegations of Paragraph 20, Count IV of the Complaint.

21. Defendants are designers, developers, manufacturers, wholesales, retailers, fabricators, suppliers and/or distributors of the multiple-dose heparin vials, one or more of which was administered to the Paul Hills during a hemodialysis session or sessions.

ANSWER:

BHC and BII admit that they manufacture and supply multiple-dose heparin vials. BHC and BII deny that they are designers, developers, wholesalers, retailers or distributors of heparin. BHC and BII are without knowledge or information sufficient to form a belief as to the allegation that heparin from their multiple dose vials was administered to Plaintiff and, therefore, deny the same.

22. The multiple-dose heparin vials were manufactured, fabricated, distributed, supplied and/or placed in the stream of interstate commerce by Defendants.

ANSWER:

BHC and BII admit that they manufacture and supply multiple-dose heparin vials. BHC and BII deny the remaining allegations of Paragraph 22, Count IV of the Complaint.

23. Defendants obtained the component parts for the multiple-dose heparin vials from unidentified supply companies, including, but not limited to, Protein Scientific Laboratories, who has two plants which supply the active pharmaceutical ingredient for heparin to Defendants.

ANSWER:

BHC and BII admit that they obtained the active pharmaceutical ingredient (API) for its multiple-dose heparin vials from Scientific Protein Laboratories. BHC and BII deny that they

obtained heparin API from any "unidentified" or "unknown" supply companies. BHC and BII are without information or knowledge sufficient to form a belief as to the remaining allegations of Paragraph 23, Count IV of the Complaint and, therefore, deny the same.

24. The active pharmaceutical ingredient in heparin is an enzyme that is extracted from pig intestines.

ANSWER:

BHC and BII admit the allegations of Paragraph 24, Count IV of the Complaint.

25. One of these plants is located in China and upon information belief, has not met the requisite requirements for importation and/or sale within the United States.

ANSWER:

BHC and BII deny the allegations of Paragraph 25, Count IV of the Complaint.

26. Such requirements include, but are not necessarily limited to, inspection and approval by the Food and Drug Administration as is required for any facility to supple [sic] drug ingredients to the United States.

ANSWER:

Paragraph 26, Count IV of the Complaint contains legal conclusions to which BHC and BII do not believe a response is due. To the extent that response is required, BHC and BII deny the allegations of Paragraph 26, Count IV of the Complaint.

27. Upon information and belief, Defendants knew or should have known of such noncompliance or lack of plant inspection and/or approval, which is required for all foreign facilities.

ANSWER:

BHC and BII deny the allegations of Paragraph 27, Count IV of the Complaint.

28. Such multiple-dose heparin vials were defective at the time they were placed in the stream of commerce.

ANSWER:

BHC and BII deny the allegations of Paragraph 28, Count IV of the Complaint.

29. Baxter knew or should have known that these multiple-dose heparin vials were defective at the time they left Baxter's control and custody.

ANSWER:

BHC and BII deny the allegations of Paragraph 29, Count IV of the Complaint.

30. Defendants also knew or should have known that the multiple-dose heparin vials were causing adverse reactions for patients, such as Paul Hills.

ANSWER:

BHC and BII deny the allegations of Paragraph 30, Count IV of the Complaint.

31. Notwithstanding their knowledge, Baxter continued to supply and sell the multiple-dose heparin vials up to and until just recently, without providing any warnings about the risks and drugs associated with the multiple-dose heparin vials to members of the public and the medical community, including Paul Hills.

ANSWER:

BHC and BII deny the allegations of Paragraph 31, Count IV of the Complaint.

32. At all material times, Baxter intentionally concealed from the public and members of the medical community, including Paul Hills, the risks and dangers associated with the use of the multiple-dose heparin vials, and/or has misrepresented the safety, quality and performance of multiple-dose heparin vials.

ANSWER:

BHC and BII deny the allegations of Paragraph 32, Count IV of the Complaint.

33. On or about January 17, 2008, Baxter and the FDA both issued press releases regarding the voluntary recall by Baxter of nine lots of Heparin Sodium Injection multiple dose vials in 1000 units/mL concentrations of 10mL and 30mL vials, 5000 units/mL concentration of 10mL vials and 10,000 units for 4mL vials.

ANSWER:

BHC and BII admit that on or about January 25, 2008, Baxter Healthcare Corporation issued a press release discussing the voluntary recall of nine lots of heparin sodium injection 1000 units/mL 10mL and 30mL multi-dose vials as a precautionary measure. BHC and BII deny the remaining allegations of Paragraph 33, Count IV of the Complaint.

34. This voluntary recall was the result of an abnormal increase in the reports of adverse patient reactions associated with the use of heparin.

ANSWER:

BHC and BII admit that Baxter Healthcare Corporation initiated the voluntary recall as a precautionary measure due to an increase in the number of reports of adverse patient reactions that may be associated with the use of heparin. BHC and BII deny the remaining allegations of Paragraph 34, Count IV of the Complaint.

35. These adverse patient reactions included the following: allergic or hypersensitivity-type reactions, with symptoms of oral swelling, abdominal pains, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, and unresponsiveness to stimul [sic], as well as cases of severe hypotension requiring treatment.

ANSWER:

BHC and BII admit that reported adverse patient reactions included oral swelling, abdominal pains, burning sensation, chest pain, diarrhea, dizziness, drug ineffectiveness, dyspepsia, dyspnea, erythema, flushing, headache, hyperhidrosis, hypoesthesia, increased lacrimation, loss of consciousness, malaise, nausea, pallor, palpitations, paresthesia, pharyngeal edema, restlessness, vomiting/retching, shortness of breath, stomach discomfort, sweating, tachycardia, thirst, trismus, hypotension, and unresponsiveness to stimuli. BHC and BII deny the remaining allegations of Paragraph 35, Count IV of the Complaint.

36. These adverse reports began as early as November 19, 2007, from more than nineteen dialysis facilities in more than twelve states.

ANSWER:

BHC and BII deny the allegations of Paragraph 36, Count IV of the Complaint.

37. An estimated 40% of the adverse reports have been categorized as serious by the FDA and there have been at least four reported deaths.

ANSWER:

BHC and BII admit that at least four deaths have been reported but deny a causal relationship between the allergic reactions involved in the heparin recall and the four fatalities. BHC and BII deny the remaining allegations of Paragraph 37, Count IV of the Complaint.

38. The bulk of the adverse reports have centered on adverse events occurring at hemodialysis centers.

ANSWER:

BHC and BII deny the allegations of Paragraph 38, Count IV of the Complaint.

39. According to the FDA, there has been a significant increase in reported adverse events associated with the use of Heparin, with an estimated 350 events reported since December 2007 in contrast to less then 100 reports in 2007.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 39, Count IV of the Complaint and, therefore, deny the same.

40. Based upon the clusters of adverse reports, Baxter and the Center for Disease Control ("CDC") initially identified nine specific Heparin manufacturing lots with a suggested link to those cases.

ANSWER:

BHC and BII admit the allegations of Paragraph 40, Count IV of the Complaint.

41. The initial nine lots recalled by Baxter ware [sic] for the following Heparin products: NDC#00641-2440-45, NDC#00641-2440-41, NDC#00641-2450-45, and NDC#00641-2450-41. The products include the following lots:

a. Heparin 1000 units/mL, 10mL vial, expiration date 10/2009, Lot #107054
b. Heparin 1000 units/mL, 10 mL vial, expiration date 11/2009, Lot #117085
c. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2008, Lot #047056
d. Heparin 1000 units/mL, 30 mL vial, expiration date 9/2009, Lot #097081
e. Heparin 1000 units/mL, 30 mL vial, expiration date 10/2009, Lot #107024
f. Heparin 1000 units/mL, 30mL vial, expiration date 10/2009, Lot #107064
g. Heparin 1000 units/mL, 30mL, expiration date 10/2009, Lot #107066
h. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107074
i. Heparin 1000 units/mL, 30 mL, expiration date 10/2009, Lot #107111

ANSWER:

BHC and BII admit the allegations of Paragraph 41, Count IV of the Complaint.

42. Upon information and belief, these nine lots were all manufactured at a single facility between September and November of 207 [sic].

ANSWER:

BHC and BII admit that the nine lots listed in Paragraph 41 were manufactured at Baxter Healthcare Corporation's Cherry Hill facility. BHC and BII deny the remaining allegations of Paragraph 42, Count IV of the Complaint.

43. Upon information and belief, the active pharmaceutical ingredient in these products was at least in part provided by a third party supplier from an unapproved facility in China.

ANSWER:

BHC and BII deny the allegations of Paragraph 43, Count IV of the Complaint.

44. However, according to FDA updates, more recent information indicates that comparable adverse events are continuing to be reported that are associated with the use of multiple-dose heparin vials of different manufacturing lots than those identified in the initial voluntary recall.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 44, Count IV of the Complaint and, therefore, deny the same.

45. The FDA began inspections of Baxter's manufacturing plant in Cherry Hill, New Jersey and its processes on or about January 16, 2008.

ANSWER:

BHC and BII admit the allegations of Paragraph 45, Count IV of the Complaint.

46. The FDA and CDC are continuing with an investigation to discover the underlying cause of these anomalous adverse events.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 46, Count IV of the Complaint and, therefore, deny the same.

47. As of February 11, 2008, Baxter ceased production of all of its multiple-dose vials of injectible heparin due to the potentially life threatening adverse and allergic reactions and incidents of hypotension that are being reported.

ANSWER:

BHC and BII deny the allegations of Paragraph 47, Count IV of the Complaint.

48. As a direct and proximate result of Defendants' defective multiple-dose heparin vials, Plaintiff has been injured and incurred substantial damages, including, but not limited to, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

ANSWER:

BHC and BII deny the allegations of Paragraph 48, Count IV of the Complaint and, therefore, deny the same.

Paul Hills

48. On or about July 24, 2007, Paul Hills had a surgical procedure performed for an abdominal aortic aneurysm at Evanston Hospital in Evanston, IL.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 48, Count IV of the Complaint and, therefore, deny the same.

49. On or about July 24, 2007, the aforesaid procedure performed on Paul Hills was successful and he was expected at that point in time to have a complete and full recovery.

ANSWER:

BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 49, Count IV of the Complaint and, therefore, deny the same.

50. On or about July 24, 2007, Paul Hills was administered the aforesaid contaminated Heparin manufactured by Baxter.

ANSWER:

The allegations of Paragraph 50, Count IV of the Complaint are vague and ambiguous. To the extent that a response is required, BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 51, Count IV of the Complaint and, therefore, deny the same.

51. Following the July 24, 2007 procedure, Paul Hills manifested signs and symptoms consistent with the administration of contaminated heparin including: dizziness, fainting, stomach pain and a fast heart rate.

ANSWER:

The allegations of Paragraph 51, Count IV of the Complaint are vague and ambiguous. To the extent that a response is required, BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 52, Count IV of the Complaint and, therefore, deny the same.

52. On and after July 24, 2007, Paul Hills had an extensive hospitalization due to complications from the contaminated heparin.

ANSWER:

The allegations of Paragraph 52, Count IV of the Complaint are vague and ambiguous. To the extent that a response is required, BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 52, Count IV of the Complaint and, therefore, deny the same.

53. On and prior to July 24, 2007, Baxter Healthcare manufactured and distributed the aforesaid contaminated Heparin product which was unreasonably dangerous for its intended use and was defective.

ANSWER:

BHC and BII deny the allegations of Paragraph 53, Count IV of the Complaint.

54. Scientific Protein Laboratories owed a duty to exercise reasonable care in the design, manufacture, testing, marketing, distributing, sale, and/or post-sale surveillance of these products, including the dose given to Paul Hills, so that it could be safely used for the purpose for which it was intended, or in a reasonable foreseeable manner.

ANSWER:

Paragraph 54, Count IV of the Complaint contains legal conclusions to which BHC and BII do not believe a response is due. To the extent a response is due, BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 54, Count IV and, therefore, deny the same.

55. This duty included the duty not to introduce a dangerous and unfit pharmaceutical drug, such as the multiple-dose heparin vials, into the stream of commerce that caused users to suffer from unreasonable, dangerous or untoward adverse side effects, up to and including death.

ANSWER:

Paragraph 55, Count IV of the Complaint contains legal conclusions to which BHC and BII do not believe a response is due. To the extent a response is due, BHC and BII are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 55, Count IV of the Complaint and, therefore, deny the same.

56. In breach of their duty of care, Scientific Protein Laboratories [sic] was negligent in the manufacturer, testing, distribution, marketing, sale, and/or post-sale surveillance of the multiple-dose heparin vials, including as follows:

a. Baxter failed to exercise reasonable care in the manufacture of their multiple-dose heparin vials;

b. Baxter failed to exercise reasonable care in the inspection of their multiple-dose heparin vials;

c. Baxter failed to exercise reasonable care in the packaging of their multiple-dose heparin vials;

d. Baxter failed to provide any and adequate warnings about the risks and dangers associated with the use of their multiple-dose heparin vials, as alleged herein;

e. Baxter failed to completely, accurately and in a timely fashion, disclose the adverse events reports associated with the use of its multiple-dose heparin vials;

f. Baxter failed to recall, withdraw, and remove their multiple-dose heparin vials from the market once they knew or should have known of the risks and dangers associated with the use thereof;

g. Baxter failed to promptly respond to data, reports, and publications describing problems associated with their multiple-dose heparin vials by conducting adequate analysis, testing, and surveillance;

h. Baxter failed to implement pre-marketing and post-marketing measures to notify and warn Paul Hills, as well as his physicians, medical providers, and other members of the medical community, of the risks and dangers associated with the use of the said multiple-dose heparin vials, and to recall the defective multiple-dose heparin vials;

i. Baxter failed to adequately and reasonably establish, maintain and comport with acceptable quality control mechanisms to prevent defective products from entering the marketplace or from using unsafe ingredients;

j. Baxter failed to adequately and reasonably ensure quality controls were in the place and as such controls were adhered to obtaining the component parts for the multiple-dose heparin vials, including, but not limited to, the active pharmaceutical ingredient;

k. Baxter failed to adequately and reasonably ensure compliance with all applicable laws, regulations, and administrative approval or licensing requirements;

1. Baxter failed to adequately monitor and/or take reasonable precautions to ensure that the active pharmaceutical ingredients in heparin were of suitable quality and safety; and

m. Baxter was otherwise negligent and careless.

ANSWER:

BHC and BII deny the allegations of Paragraph 56, Count IV of the Complaint including all allegations in subparts 56(a-m).

57. Baxter knew or should have known that patients/consumers such as Paul Hills would foreseeably suffer injury as a result of their failure to exercise ordinary care as described above.

ANSWER:

BHC and BII deny the allegations of Paragraph 57, Count IV of the Complaint.

58. Baxter's multiple-dose heparin vials were expected to and did reach Paul Hills without substantial change in the condition as designed, manufactured, marketed, distributed, and sold, prior to their administration to Paul Hills, who used the heparin as intended, or in a reasonably foreseeable manner.

ANSWER:

BHC and BII deny the allegations of Paragraph 58, Count IV of the Complaint.

59. Baxter's negligent conduct caused substantial harm to Paul Hills.

ANSWER:

BHC and BII deny the allegations of Paragraph 59, Count IV of the Complaint.

60. As a direct and proximate result of this defective product, Plaintiff has been injured and incurred substantial damages, including, but not limited to, medical and hospital expenses, loss of income, physical and mental pain and suffering, loss of enjoyment of life, and other damages for which Defendants are liable.

ANSWER:

BHC and BII deny the allegations of Paragraph 60, Count IV of the Complaint.

WHEREFORE, plaintiff, PAUL HILLS, by his attorneys, POWER ROGERS & SMITH, demands judgment against Defendant, SCIENTIFIC PROTEIN LABORATORIES, in such sum of money in excess of FIFTY THOUSAND DOLLARS ($50,000.00) as shall represent fair and just compensation.

ANSWER:

BHC and BII deny that Plaintiff is entitled to the relief sought in the final Paragraph of Count IV of the Complaint, or any relief whatsoever from BHC and BII.

AFFIRMATIVE DEFENSES

FIRST DEFENSE

The Complaint fails to state a claim against BHC and BII upon which relief may be granted.

SECOND DEFENSE

The Complaint fails to give fair notice of Plaintiff's claims are and the grounds upon which those claims rest. *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955 (2007).

THIRD DEFENSE

Plaintiff's claims, if any, that may be based on misrepresentation or fraud against BHC and BII must be barred because Plaintiff failed to state with particularity the circumstances constituting the alleged fraud or misrepresentation as required by Fed. R. Civ. P. 9 and the common law of Illinois. *See* e.g. *Hirsch v. Fever*, 299 Ill. App. 3d 1076, 1085, 702 N.E.2d 265, 272 (Ill. App. 1 Dist., 1998).

FOURTH DEFENSE

The Complaint, and each and every purported cause of action asserted against BHC and BII is barred, in whole or in part, by Plaintiff's failure to join indispensable parties.

FIFTH DEFENSE

Plaintiff's claims are barred in whole or in part by the doctrines of comparative and/or contributory negligence.

SIXTH DEFENSE

If there is any actionable liability of BHC and BII, which liability they specifically deny, such liability should be compared to the fault of Plaintiff, parties, and actors involved in the matters alleged in Plaintiff's Complaint. BHC and BII allege that any award made to Plaintiff in this action must be proportionately allocated among the Plaintiff, BHC and BII, parties or actors found to be culpable in accordance with the percentage of any negligence or fault attributable to each of said Plaintiff, BHC and BII, parties and actors. BHC and BII further allege that any party or actor found to be negligent or at fault with respect to Plaintiff's alleged claims must be required to satisfy any such claims only in accordance with its proportional share of negligence or fault to be determined in this action.

SEVENTH DEFENSE

Plaintiff's comparative negligence in causing his injuries is equal to or in excess of fifty percent of the total negligence that caused the harm alleged by Plaintiff, and therefore, any recovery by Plaintiff is barred pursuant to 735 ILCS 5/2-1116(c).

EIGHTH DEFENSE

Plaintiff's alleged injuries were not caused legally, proximately, or in-fact by BHC and BII or any acts or omissions of BHC and BII.

NINTH DEFENSE

Plaintiff's alleged injuries were proximately caused by the superseding and intervening acts of third parties other than BHC and BII and over which BHC and BII had no control and for which BHC and BII are not liable.

TENTH DEFENSE

Plaintiff's alleged injuries were directly and proximately caused and contributed to by the acts, omissions, and/or negligence of persons other than BHC and BII, whether individual, corporate, associate, or otherwise, over whom BHC and BII had no control or authority.

ELEVENTH DEFENSE

Plaintiff's alleged injuries were caused or contributed to, directly and proximately, by the misuse, abuse, alteration, unauthorized use, unintended use, and/or failure properly to utilize, maintain or care for the products that Plaintiff alleges were manufactured and/or distributed by BHC and BII, if manufactured and/or distributed by BHC and BII, without negligence, strict tort liability, lack of care or any other breach of duty on the part of BHC and BII, and for which BHC and BII are not liable.

TWELFTH DEFENSE

Plaintiff's alleged injuries were caused or contributed to, directly and proximately, by the contributory negligence of Paul Hills or others that are attributable to them. BHC and BII therefore plead the doctrine of comparative negligence.

THIRTEENTH DEFENSE

Plaintiff's alleged injuries were caused or contributed to, directly and proximately, in whole or in part, by operation of nature or by an Act of God without negligence, strict tort liability or lack of care or any other breach of duty on the part of BHC and BII, for which BHC and BII are not liable.

FOURTEENTH DEFENSE

Plaintiff's alleged injuries were directly and proximately caused and contributed to by the actions of other persons, who caused changes and alterations to be made to the products that

Plaintiff alleges were manufactured and/or distributed by BHC and BII, if manufactured and/or distributed by BHC and BII, and said changes and alterations proximately caused or contributed to Plaintiff's alleged injuries.

FIFTEENTH DEFENSE

Plaintiff's claims are barred in whole or in part by the doctrine of assumption of the risks inherent in using a pharmaceutical product.

SIXTEENTH DEFENSE

At all relevant times, the methods, standards and techniques utilized in the manufacturing, design, testing and marketing of the product that Plaintiff alleges was manufactured and/or distributed by BHC and BII, as well as any warnings issued or instructions provided with respect to the use of the product, conformed with the generally recognized, reasonably available, and reliable state of the art and the state of medical and scientific knowledge.

SEVENTEENTH DEFENSE

The learned intermediary doctrine is applicable to and bars Plaintiff's claims. At all times relevant hereto, Paul Hills' treating physicians, and other relevant learned intermediaries, if any, were provided proper, complete, and adequate warnings and instructions consistent with the state of medical art and knowledge.

EIGHTEENTH DEFENSE

At all relevant times hereto, the product Plaintiff alleges was manufactured and/or distributed by BHC and BII was a prescription medical product deemed unavoidably unsafe, in the sense of Restatement (Second) of Torts § 402A, Comment k, and Restatement (Third) Torts:

Products Liability § 6, such that Plaintiff's claims are barred, in whole or in part, by the doctrines concerning unavoidably unsafe agents and/or strict liability.

NINETEENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, because the danger, or potential danger, concerning the product Plaintiff alleges was manufactured and/or distributed by BHC and BII were generally known and recognized, and the product was a prescription medical product falling within what is commonly known as "Comment j" in the Restatement (Second) of Torts § 402A.

TWENTIETH DEFENSE

Plaintiff's claims are barred, in whole or in part, because BHC and BII complied with all applicable product safety statutes and/or administrative regulations, and the product Plaintiff alleges was manufactured and/or distributed by BHC and BII was a prescription medical products falling within the Restatement (Third) of Torts: Products Liability § 4 and comments thereto.

TWENTY-FIRST DEFENSE

BHC and BII deny, to the extent the actions alleged in the Complaint may have occurred, that any entity engaging in the activities alleged was acting as the agent or servant of BHC and BII, or at the instruction or subject to the control of BHC and BII with regard to any of the actions described in the Complaint; thus, BHC and BII are not liable for any acts or omissions of such third parties as a matter of law.

TWENTY-SECOND DEFENSE

The conduct of BHC and BII and the alleged subject product at all times conformed with the Federal Food, Drug and Cosmetic Act, and other pertinent federal statutes and regulations.

Accordingly, Plaintiff's claims are barred, in whole or part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations and policies in violation of the Supremacy Clause of the United States Constitution.

TWENTY-THIRD DEFENSE

To the extent that the Complaint seeks punitive damages, BHC and BII specifically incorporate by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damage awards which arose in the decisions of *BMW of N. Am. v. Gore,* 116 U.S. 1589 (1996,), *Cooper Indus., Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001), *State Farm Mut. Auto Ins. Co. v. Campbell,* 538 U.S. 438 (2003), and their progeny.

TWENTY-FOURTH DEFENSE

To the extent that the Complaint seeks punitive damages, BHC and BII assert that any claims for punitive damages are barred by the Fifth, Eighth, and Fourteenth Amendments of the United States Constitution and Article 1, Sections 2, 10 and 11 of the Constitution of the State of Illinois.

TWENTY-FIFTH DEFENSE

The alleged claims or causes of action attempted to be asserted against BHC and BII are barred by the applicable statues of limitations and statutes of repose.

TWENTY-SIXTH DEFENSE

BHC and BII did not participate in, authorize, ratify or benefit from the alleged wrongful acts asserted in the Complaint.

TWENTY-SEVENTH DEFENSE

Plaintiff's claims are barred in whole or in part by the Plaintiff's failure to mitigate damages.

TWENTY-EIGHTH DEFENSE

Plaintiff's causes of action are barred, in whole or in part, by the doctrines of laches, waiver, and estoppel.

TWENTY-NINTH DEFENSE

The Complaint, and each and every purported cause of action asserted against BHC and BII, is barred, in whole or in part, because BHC and BII were released as to the conduct alleged in the Complaint.

THIRTIETH DEFENSE

Plaintiff's alleged injuries were the result of pre-existing or subsequent conditions of Paul Hills, which were without negligence, strict tort liability, lack of care or any other breach of duty on the part of BHC and BII, and for which BHC and BII are not liable.

THIRTY-FIRST DEFENSE

Plaintiff's alleged injuries were the result of an idiosyncratic reaction that BHC and BII could not reasonably foresee and were without negligence, strict tort liability or lack of care or any other breach of duty on the part of BHC and BII, and for which BHC and BII are not liable.

THIRTY-SECOND DEFENSE

Plaintiff's product liability causes of action are barred because the benefits of the product that Plaintiff alleges was manufactured and/or distributed by BHC and BII, if manufactured and/or distributed by BHC and BII, outweighed its risks.

THIRTY-THIRD DEFENSE

To the extent that Plaintiff's claims are based upon any theory providing for liability without proof of causation by BHC and BII, they violate BHC and BII' rights under the United States Constitution and Illinois Constitution.

THIRTY-FOURTH DEFENSE

The Complaint, and each and every purported cause of action asserted against BHC and BII, is barred, in whole or in part, because BHC and BII have and are complying with all applicable requirements of law including but not limited to 21 U.S.C.A. § 360k.

THIRTY-FIFTH DEFENSE

Plaintiff's claims for damages, if any, are barred because such damages, to the extent they exist, are speculative, uncertain, and vague.

THIRTY-SIXTH DEFENSE

Upon information and belief, each item of economic loss alleged in the complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part by collateral sources, for which BHC and BII are entitled to a set-off against any judgment entered against BHC and BII.

THIRTY-SEVENTH DEFENSE

No product manufactured by BHC and BII was unreasonably dangerous or defective in design, manufacture or information accompanying the product.

THIRTY-EIGHTH DEFENSE

Plaintiff is not entitled to recover from BHC and BII because Plaintiff, his agents, or intervening third parties of their choice, had the same notice and knowledge as BHC and BII

with respect to the alleged hazard or defect, if any, in the product Plaintiff alleges was manufactured and/or distributed by BHC and BII.

THIRTY-NINTH DEFENSE

BHC and BII reserve the right to assert any additional defenses which may arise as discovery progresses or otherwise in the course of the litigation.

WHEREFORE, Defendant Baxter International Inc. and Baxter Healthcare Corporation respectfully pray:

1. The Plaintiff take nothing in this action;
2. For costs of suit incurred in this action, including attorneys' fees; and,
3. For such other and further relief as the Court may deem just and proper.

Dated this 10th Day of June, 2008

Respectfully submitted,

/s/ Leslie M. Smith, P.C.

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CERTIFICATE OF SERVICE

I, Leslie M. Smith, P.C. do hereby certify that on June 10, 2008, I caused a copy of the foregoing **ANSWER OF BAXTER HEALTHCARE CORPORATION AND BAXTER INTERNATIONAL INC.** to be served on Plaintiff's counsel by overnight delivery:

Devon C. Bruce
POWER, ROGERS & SMITH
70 West Madison Street, Suite 5500
Chicago, IL 60602
telephone (312) 236-9381
facsimile: (312) 236-0920

This 10th day of June, 2008.

/s/ Leslie M. Smith, P.C.
Leslie M. Smith, P.C.